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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,173

05/16/2005

Claude Mialhe

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5752

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08/25/2009

YOUNG & THOMPSON

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EXAMINER

DANG, PHONG SON H

ART UNIT

PAPER NUMBER

3773

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/535,173	MIALHE, CLAUDE	
	<b>Examiner</b>	<b>Art Unit</b>	
	SON DANG	3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5,9-13 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,9-13 and 16-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/14/2009 has been entered.

2. The amendment filed 07/14/2009 has been entered. Claims 4, 6-8, 14-15 have been cancelled. Claims 19-20 have been added. Claims 1-3, 5, 9-13, 16-20 are currently pending in the application.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 5, 13 and 19-20 are rejected under 35 U.S.C. 102(e) as being anticipated by US PG PUB No. 2004/0019374 to Hojeibane et al. (Hojeibane).

In Regards to claims 1-3, 5, 9-13 and 16-20:

Hojeibane teaches:

A vascular occlusion device comprising: an occlusive device (100, Fig. 1A) having a hollow cylindrical element (105, Fig. 1A) that can be twisted (Fig. 1C) to its axis to create a striction zone, comprising a transverse compression deformable body (102, Fig. 1A) applied to the inner wall (paragraph 124) of the cylindrical element (105, Fig. 1A), comprising a through hole according to axis of the cylindrical element (105, Fig. 1A), and the device further comprising two end parts (103, 104, Fig. 1A), surrounding the cylindrical element (105, Fig. 1A) and whose relative angular position determines the torsion of said cylindrical element (105, Fig. 1A), said end parts (103, 104, Fig. 1A) possessing means of attachment to the wall of a vessel, the attachment means are expanding elements (Fig. 1A). The deformable body (102, Fig. 1A) is attached to the inner wall (paragraph 124) of the cylindrical element (105, Fig. 1A). The deformable body (102, Fig. 1A) is made from a polymer material (paragraph 14). Cylindrical element (105, Fig. 1A) and the deformable body (102, Fig. 1A) both have circular cross sections. A peripheral obturation web (Fig. 5B, when closing, the prosthetic venous valve creates a web like structure) extending from one end of the deformable (102, Fig. 1A) body and the edge of the expanding element (103, 104, Fig. 1A). A removable sleeve (inherently needed for deliver the device into the body to carry out the procedure) surrounding the occlusive device (100, Fig. 1A). The deformable body (102, Fig. 1A) and the cylindrical element (105, Fig. 1A) are distinct parts.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hojeibane in view of US Patent No. 5,843,160 to Rhodes (Rhodes).

Hojeibane teaches:

The device according to claim 1 (see rejection of Claim 1 above).

Hojeibane fails to teach:

The device comprising comprising a seal on the outer surface of at least one of the expanding elements, said seal being appropriate for application to the wall of a vessel.

Rhodes teaches:

The device (20, Fig. 1) comprising a seal (30, Fig. 1, Col. 9, lines 34-41) on the outer surface of at least one of the expanding elements (36, Fig. 1, Col. 8, line 25) said seal being appropriate for application to the wall of a vessel.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the seal in order to prevent leakage of body fluid.

7. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojeibane in view of US Patent No. 6,425,916 to Garrison et al. (Garrison).

In Regards to claims 11-12:

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Hojeibane teaches:

The device according to claim 1 (see rejection of claim 1 above),

Hojeibane fails to teach:

A removable guide positioned according to the axis of the cylindrical element and crossing the hole in the deformable body.

A removable sheath inserted between the wall of the hole in the deformable body and the outer wall of the guide.

Garrison teaches:

A removable guide (72, Fig. 14) positioned according to the axis of the cylindrical element (8, Fig. 14) and crossing the hole in the deformable body (6A, Fig. 14).

A removable sheath (78, Fig. 14) inserted between the wall of the hole in the deformable body (6A, Fig. 14) and the outer wall of the guide (78, Fig. 14),

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the delivery device for a prosthetic device of Garrison into Hojeibane merely as a substitution for a delivery means that would perform expectable results.

8. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojeibane in view of US Patent No. 6,168,619 to Dinh et al. (Dinh).

In Regard to claims 16-18:

Hojeibane teaches:

The device according to claims 1 and 3 (see rejections of claims 1 and 3 above), wherein a frame having a first central zone constituting the cylindrical

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element (105, Fig. 1A) and two zones around the first zone, said two zones constituting expanding elements (103, 104, Fig. 1A).

Hojeibane fails to teach:

The polymer material has shape memory properties. The expanding elements are self-expanding frames. A Nitinol based metallic frame.

Dinh teaches:

The polymer material has shape memory properties. The expanding elements are self-expanding frames. A Nitinol based metallic frame (Col. 1, lines 12-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the frame of Dinh into Hojeibane in order to sustain the self-expanding and shape memory properties for the frame, and it is well known in the art that such self-expansion would reduce time for frame deployment during a procedure.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hojeibane in view of US PG PUB No. 20020032481 to Gabbay (Gabbay).

In Regards to claim 20:

Hojeibane teaches:

The device according to claim 1 (see rejection of claim 1 above).

Hojeibane fails to teach:

The deformable body has a thickness greater than the thickness of the cylindrical element.

Gabbay teaches:

The deformable body (50, Fig. 4) has a thickness greater than the thickness of the cylindrical element (54, Fig. 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the thickness of the valve in order to enhance the rigidity of the body and reinforcement to the area.

### ***Response to Arguments***

10. Applicant's arguments with respect to claims 1-3, 5, 9-13, 16-20 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809. The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SD

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

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